

## REMARKS

This response is submitted in reply to the Office Action mailed February 19, 2009 ("the Action"). A three month extension of time is being submitted herewith. Claims 1-23 and 34 were pending in the application and stand rejected as being obvious over U.S. 2002/0193685 to Mate et al. ("Mate") in view of U.S. Patent No. 5,142,930 to Allen et al. ("Allen") or in further view of WO 97/33513 to Iddan ("Iddan").

### I. Claims 1-3, 5-7, 10, 13-18, 20-23 and 34

The Action states that Mate teaches a target locating an *in vivo* sensor system used with a therapy delivery and an imaging source, an external solenoid, and at least one implantable wireless unit with a solenoid that generates a coupling signal that varies based on the position of the external solenoid relative to the implanted unit. The Action concedes that Mate does not teach a mechanism configured to controllably move the solenoid and a controller which directs the movement of the mechanism. However, the Action states that Allen teaches these features and alleges that one of skill in the art would have found it obvious to modify Mate to include a mechanism to control movement of the solenoid per Allen "because the multi-joint mechanical arm can freely rotate and move in three dimensional [space?]....a more effective way to keep track of the moving solenoid inside the body" (Action, p. 3). Applicant respectfully disagrees.

Mate proposes a Guided Radiation Therapy System with an internal marker and a computer that controls movement of the patient and a patient support device so that the target isocenter is co-incident with the machine isocenter (Abstract). Allen proposes an Interactive Image Guided Surgical System that causes a display device to display the location of the surgical tool within the image space. Allen proposes the use of fiducial implants that will not move or change their spatial relationship with respect to each other over time to define an internal coordinate system (col. 2, lines 54-60). Allen states that, regardless of the reason why the patient is oriented differently, by taking advantage of the fixed internal coordinate system in the anatomy, the location and direction of the plane defined by the three fiducial

implants in the first imaging session can be compared with that of a second imaging session (col. 3, lines 29-46). Thus, the location of the fiducial implants in different scan planes in different imaging sessions can determine the location and orientation of the implants and the location of a moving point (*e.g.*, laser held at the end of the arm) is continuously followed (*see*, col. 3, lines 50-55). The arm has position encoders so that the location of the surgical tool attached to the arm will be known with respect to the internal coordinate system (col. 2, lines 11-14). Applicant submits that Allen does not electrically couple the encoders with the fiducial implants to provide a coupling signal that determines position of the implants at all. Indeed, Allen uses images and scan planes with position encoders and different coordinate systems to track surgical tools for image guided systems.

Clearly, Mate and Allen work in very different ways. Absent the teachings of the present invention, one of skill in the art would not have modified Mate to use the arm of Allen, much less in the manner alleged by the Action.

In addition, if properly combinable, the system of Mate would appear to be modified to use a moving arm and also to replace the internal marker with fixed non-moving implanted fiducial makers to define an internal coordinate system for an image guided system. Indeed, it is improper to select isolated features from different patents based on the teachings of the instant application.

Further, Mate proposes a number of ways to identify the location and movement of the marker in the body, *see, e.g.*, the array of markers (Figure 4). Notably, despite the fact that Allen issued almost 10 years before the filing date of Mate, Mate fails to teach or suggest the use of a moving mechanism with an external solenoid that couples to the internal solenoid to identify position of the internal sensor/marker. Clearly, incorporating a mechanical arm that cooperates with the internal solenoid to generate a coupling signal to determine position is very different from the systems proposed by Mate or Allen. For example, embodiments of the present invention determine the location using a coupling signal variation which is dependent on the application of energy from and movement of the external solenoid with respect to the internal sensor/solenoid. Further, even combined, the references fail to teach or suggest sensing an internal parameter as well as providing spatial data as recited in method

Claim 23.

The independent claims are restated below for ease of discussion.

1. A target locating and *in vivo* sensor system adapted for use with a therapy delivery and/or imaging source, comprising:  
an external solenoid member;  
a mechanism operably associated with the external solenoid member, wherein, in operation, the mechanism is configured to controllably move the solenoid external of a patient;  
a controller configured to direct the movement of the mechanism, the controller being in communication with a power source configured to power the external solenoid;  
at least one implantable wireless unit comprising a solenoid, wherein, in operation, the unit solenoid held internally in the patient cooperates with the external solenoid to generate a coupling signal having a signal strength that varies based on the position of the external solenoid member relative to the implanted unit; and  
a computer module in communication with the controller comprising computer program code that evaluates the coupling signal strength in relation to the position of the external solenoid and determines the position of the at least one internally implanted unit.

23. A method of obtaining spatial data and radiation dose data regarding a target *in vivo* treatment site, comprising:  
sensing *in vivo* at least one predetermined parameter of interest in a patient using at least one implanted sensor unit;  
wirelessly transmitting data associated with the sensed at least one parameter from the at least one sensor unit to an external reader;  
moving an articulating arm about the patient in a three-dimensional pattern, the articulating arm having an associated coupling member located external of the patient proximate the target treatment site, the coupling member being configured to cooperate with the at least one implanted sensor to generate a coupling signal with a signal strength that varies in relation to the position of the coupling member with respect to the at least one sensor unit;  
detecting the signal strength of the coupling signal at a plurality of locations traveled based on the moving step; and  
determining the position of the at least one sensor unit in the body based on the detecting step, thereby having the implanted sensor unit act as a positional marker and an *in vivo* sensor.

34. A computer program product for obtaining spatial data regarding the position of at least one implanted sensor, the computer program product comprising:  
computer readable storage medium having computer readable program code embodied in said medium, said computer-readable program code comprising:  
computer readable program code for determining the spatial location of a selected one of the at least one implanted sensor units using input data associated with variation in signal strength of a coupling signal generated by an external solenoid and the at least one sensor unit over different known external positions of the external solenoid.

Applicant respectfully submits that Claims 1, 23 and 34 are patentable for at least the reasons discussed above and the emphasized features noted in these claims, which are not taught or suggested by the cited art. Further, Applicant respectfully submits that dependent claims are also patentable at least for depending from a patentable base claim. Applicant also submits that the dependent claims recite independently patentable subject matter.

For example, even combined, Applicant respectfully submits that the cited art fails to teach or suggest the subject matter of Claims 15 and 16.

15. A system according to Claim 1, wherein the external solenoid generates a signal shape that varies with spatial and angular orientation with the internal solenoid of the sensor unit, and wherein said computer module comprises computer program code that evaluates the generated signal strength and deconvolutes the signal shape with respect to position to determine the spatial location of the sensor in the subject.

16. A system according to Claim 15, wherein the controller directs the mechanism to move the solenoid through a three dimensional pattern in free space to generate a corresponding response coupling signal, and wherein the computer module program code that evaluates the coupling signal strength uses the response signal generated by the three dimensional pattern to determine the position of the sensor unit.

Thus, Applicant respectfully submits that the dependent claims, including, *inter alia*, Claims 15 and 16 are patentable over the cited prior art.

In addition, Mate proposes a measureable signal in the range of approximately 10kHz to 200kHz (para. 45). Claim 20 recites that the range is between about 500kHz and 1MHz (*see, e.g.*, p. 16 of the pending application), this range is above the range taught by Mate. Applicant submits that Claim 20 is also patentable over the cited prior art.

## **II. Claims 4, 8-9, 11-12 and 19**

The Action concedes that, even combined, Mate and Allen fail to teach communicating with implanted sensor units using a bit encoded RF signal, or sensors with sensing parameters for temperature and radiation dose. However, Iddan is cited for teaching the use of a bit encoded RF signal and sensors.

First, Applicant was unable to find where WO 97/33513 lists "Iddan" as an inventor or as an Applicant. In addition, page 3 of this document discusses an integrated spectrophotometer. Applicant was unable to find a discussion of an external reader or a bit encoded RF signal on page 3 of the WO 97/33513 document. Applicant requests that the Examiner provide more specific citations of support for this position and/or correct the citation to a different reference.

## **III. New Claims**

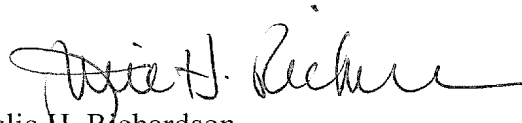
Applicant has added new dependent claims corresponding to some of the original filed claims that were canceled in a preliminary amendment to reduce filing fees. Support for these claims can be found in the original claims as well as the original specification and/or figures. Applicant respectfully submits that these claims define over the cited prior art and consideration of these claims is requested.

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Filed: August 29, 2006  
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### CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,



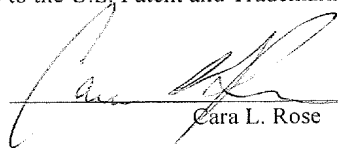
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### CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on August 4, 2009.

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Cara L. Rose